

buffer (PBS) and 10 mg/cm³ of ovalbumin.” As noted in the Office Action, nine other mannitan oleate compositions are listed in the Table in addition to Composition H. The difference between Composition H and the other nine mannitan oleate compositions is the poly-ethoxylated derivative of mannitan oleate. As stated on page 7, lines 5-7, “As an example of [the composition of the present invention], there is the one in which the surfactant is an ethoxylated derivative of mannitan oleate having a number of EOs of between 5 and 15, preferably between 7 and 11.” The term “EO” is utilized with its generally accepted definition as a unit of an ethoxylation indice. As shown in the Table, Composition H has an ethoxylation indice of 8 EOs.

As basis for the rejection under 35 U.S.C. § 112, first paragraph, the Office Action purports:

Also note that it is apparent that the calculation of “HLB” numbers is essential to the claimed invention. However, for the calculation of said numbers the specification merely refers to “the European Pharmacopoeia.” Said reference is improper and comprises a further absence of essential material.

Applicants respectfully submit that HLB numbers (i.e., hydrophile-lipophile balance numbers) are well known in the art, particularly with regard to surfactant properties. As recited on page 5, lines 12-16, of the specification:

For the purpose of the present invention, the HLB number is calculated using the formula $HLB = 20 (1 - I_s/I_a)$, in which I_s represents the saponification index and I_a represents the acid index of said surfactant or of said mixture of surfactants. These two indices, saponification and acid indices, are determined by methods described in the European Pharmacopoeia.

One of skill in the art would be familiar with HLB numbers, the saponification index and the acid index of surfactants and the determination of same. That the concepts of saponification index and acid index are not specifically defined in the specification, does not make the specification any less complete as one of skill in the art would not require further discussion of these concepts in order to understand the invention. These concepts are well known in the art. For example, with regard to the acid index, Section 2.5.1 of the European Pharmacopoeia states:

The acid value I_a is the number that expresses in milligrams the quantity of potassium hydroxide required to neutralise the free acids present in 1 g of the substance. . . . Dissolve 10.00 g of the substance to be examined, or the quantity prescribed (m g) in 50 ml of a mixture of equal volumes of alcohol R and ether R, previously neutralised with 0.1 M potassium hydroxide, unless otherwise specified, using 0.5 ml of phenolphthalein solution R1 as indicator. When the substance to be examined has dissolved, titrate with 0.1 M potassium hydroxide

until the pink colour persists for at least 15 s (n ml of 0.1 M potassium hydroxide).

As another example, with regard to the saponification index, Section 2.5.6 of the European Pharmacopoeia states:

The saponification value I_s is the number that expresses in milligrams the quantity of potassium hydroxide required to neutralise the free acids and to saponify the esters present in 1 g of the substance. . . . Unless otherwise prescribed, use the quantities indicated in table 2.5.6.-1 for the determination. . . . Introduce the prescribed quantity of the substance to be examined (m g) into a 250 ml borosilicate glass flask fitted with a reflux condenser. Add 25.0 ml of 0.5 M alcoholic potassium hydroxide and a few glass beads. Attach the condenser and head under reflux for 30 min, unless otherwise prescribed. Add 1 ml of phenolphthalein solution R1 and titrate immediately (while still hot) with 0.5 M hydrochloric acid (n1 ml of 0.5 M hydrochloric acid). Carry out a blank test under the same conditions (n2 ml of 0.5 M hydrochloric acid).

Applicants respectfully submit that the foregoing comments traverse the rejection of claims 19-20 and 30-32 under 35 U.S.C. § 112, first paragraph, as allegedly being based on a disclosure which is not enabling. Applicants respectfully request that the rejection be removed and the claims allowed. Should the Examiner have any remaining questions or comments, he is invited to contact the undersigned attorney at the below listed telephone number.

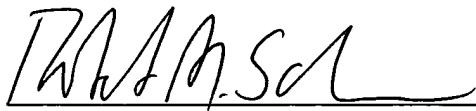
In the event any variance exists between the amount enclosed and the Patent Office charges, please charge or credit any difference to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

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